IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Melton B. Affrime, *et al.* :

Application No.: 09/760,588 : Group Art Unit: 1614

Filed: January 16, 2001 : Examiner: C. Delacroix-Muirheid

For: TREATING ALLERGIC AND INFLAMMATORY CONDITIONS :

Commissioner for Patents
Washington, D.C. 20231

RESPONSE UNDER 37 C.F.R. § 1.116

Sir:

This paper is responsive to the Office Action mailed November 20, 2002, and is filed prior to the expiration of the six-month statutory period for response and in conjunction with the Request for Continued Examination filed herewith. Applicants respectfully request reconsideration and withdrawal of the grounds of rejection set forth in the Office Action.

REMARKS

This Response responds to the Office Action mailed November 20, 2002. Claims 1-9, 11-20, 22-25, 27-39, 41-46, 48, 49, and 51-64 are pending in the Application. Claims 1-9, 11-18, 24, 25, 27, 28, 31-39, 41-46, 48, 49, and 51-60 stand rejected under 35 U.S.C. § 103(a). Claims 19, 20, 22, 23, 29, 30, and 61-64 have been allowed.

A. Rejections Under 35 U.S.C. § 103(a)

Claims 1-9, 11-18, 24, 25, 27, 28, 31-39, 41-46, 48, 49, and 51-60 stand rejected under 35 U.S.C. § 103(a) as obvious in light of United States Patent No. 5,962,464 (Handley, *et al.*) and United States Patent No. 5,595,997 (Aberg, *et al.*) in view of D. Padhi, *et al.*, *Multiple-Dose Pharmacokinetics, Safety, and Tolerance of Desloratadine in Healthy Volunteers* (Abstract

1124), J. Allergy Clin. Immunol., Vol. 105, No. 1, part 2, p. S385 (January 2000), and J. M. Herron, *et al.*, *Dose-Proportionality, Linearity, and Pharmacokinetics of Desloratadine in Healthy Volunteers* (Abstract 1126), J. Allergy Clin. Immunol., Vol. 105, No. 1, part 2, p. S385 (January 2000). Specifically, the Examiner opined that because Handley, *et al.*, and Aberg, *et al.*, disclosed methods for treating certain allergic disorders comprising administering effective amounts of desloratadine and because Padhi, *et al.*, and Herron, *et al.*, disclosed certain pharmacokinetic findings regarding desloratadine,

> it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Handley and Aberg to administer desloratadine such that the claimed plasma concentrations are achieved because Padhi and Herron et al. raise reasonable expectation of success [sic] by establishing that there is a correlation between the efficacy and tolerability of desloratadine and it's [sic] pharmacokinetics . . . [and] to further modify the methods of Handley and Aberg such that desloratadine is administered in an amount and for a time that is effective to optimize its effect on the allergic disorders being treated.

Office Action at 4-5.

Applicants respectfully disagree with the Examiner's rejection of claims 1-9, 11-18, 24, 25, 27, 28, 31-39, 41-46, 48, 49, and 51-60 under section 103(a). Applicants respectfully submit that Padhi, *et al.*, and Herron, *et al.*, do not qualify as prior art under 35 U.S.C. § 102.

The above-captioned application claims priority to United States provisional patent application serial no. 60/179,910, which was filed on February 3, 2000. *See* Declaration, dated January 16, 2001, a copy of which is attached as Exhibit A. Padhi, *et al.*, and Herron, *et al.*, published (at the earliest) less than a month before the priority date of this application.

Applicants (Melton Affrime, Christopher Banfield, Samir Gupta, and Desmond Padhi) are four of the co-authors of Padhi, *et al.*, and of Herron, *et al.* Melton Affrime, Christopher Banfield, Samir Gupta, and Desmond Padhi are the co-inventors of the claimed

invention. *See* Request to Correct Inventorship and Declaration filed herewith. As explained in the declaration of Dr. Gupta accompanying this Response, the other two co-authors, Drs. Herron and Glue, are not inventors of the claimed invention. *See* Declaration of Dr. Samir Gupta, attached as Exhibit B. In particular, Dr. Herron was a clinician at the Arkansas Research Medical Testing Center, where the clinical study was conducted. He administered the clinical study under the direction and supervision of Melton Affrime, Christopher Banfield, Samir Gupta, and Desmond Padhi. *Id.* at ¶5. Dr. Glue monitored and addressed potential adverse event issues relating to the safety of participants in the clinical study. *Id.* at ¶6. These potential adverse event issues did not relate to the claimed invention. *Id.* Thus, all relevant portions of Padhi, *et al.*, and Herron, *et al.*, were conceived by Applicants. Accordingly, neither Padhi, *et al.*, nor Herron, *et al.*, qualifies as prior art under sections 102(a) or (b) or any other subsection of section 102, and therefore may not properly be combined with Handley, *et al.*, or Aberg, *et al.*, to form a basis for rejecting claims of the present application. *See Katz*, 215 U.S.P.Q. (BNA) at 17-18 (authorship of an article does not raise a presumption of inventorship); MPEP §§ 715.01(c); 716.10.

Applicants therefore respectfully submit that no *prima facie* case of obviousness has been made and that claims 1-9, 11-18, 24, 25, 27, 28, 31-39, 41-46, 48, 49, and 51-60 are patentable. Reconsideration and withdrawal of this ground of rejection are urged.

Applicants agree with the Examiner's conclusion that claims 19, 20, 22, 23, 29, 30, and 61-64 claim allowable subject matter.

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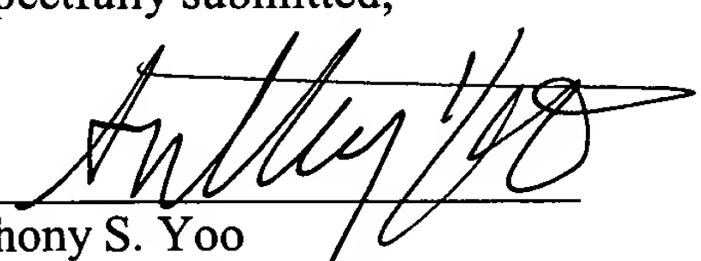
If the undersigned attorney for applicants can be of any assistance in advancing the prosecution of the Application, please call him at 202-662-5571.

Dated: May 14, 2003

Respectfully submitted,

By 

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